

## 510(k) Summary

**Trade Name:** Total Etch Bonding Agent (Total-Etch Bond & Total-Etch Dual-Bond)

**Sponsor:** DMG USA, Inc.  
23 Frank Mossberg Drive  
Attleboro, MA 02703  
Registration # not yet assigned  
Owner/Operator No. 9005969

March 1, 2007

**Device Generic Name:** Dental Bonding Agent

**Classification:** According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

### Product Description:

The Total Etch Bonding Agent consists of two dental bonding agent formulations for use in dual- and light-cured bonding procedures:

Total-Etch Bonding Agent for Dual-Cured Resin-Based Materials (Total-Etch Dualbond)  
Total-Etch Bonding Agent for Light-Cured Resin-Based Materials (Total-Etch Bond)

### Indications for Use:

**Total-Etch Dualbond** is indicated for

- Bonding resin-based materials (especially dual cure composite, compomer materials) to tooth structure (dentin and enamel)
- Treatment of hypersensitive teeth

**Total-Etch Bond** is indicated for

- Bonding resin-based materials (especially light cure composite, compomer materials) to tooth structure (dentin and enamel)
- Treatment of hypersensitive teeth

### Predicate Devices:

The components of the proposed Post and Core Kit materials are substantially equivalent to several currently marketed dental restorative materials including the following:

#### Total-Etch Dualbond:

Product Name	Predicates
Excite DSC	K003293 (Ivoclar North America Inc.)
Optibond Solo Plus (Dual-cure)	Unknown (Kerr Mfg. Co.)
All Bond 2	K910628 (Bisco)
Scotchbond MP Plus	K942493 (3M Espe)

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**Total-Etch Bond:**

Product Name	Predicate
Contax bonding agent contained in the DMG Composite / Compomer Repair Kit	K041960 (DMG - USA)

**Safety and Performance:**

This submission contains safety and performance information (chemical composition and physical performance data) sufficient to establish substantial equivalence in comparison to the devices listed above.

**Conclusion:**

Based on the indications for use, technological characteristics, and comparison to the predicate devices, the Total Etch Bond has been shown to be safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DMG USA, Incorporated  
C/O Ms. Pamela Papineau  
Regulatory Affairs Consultant  
Delphi Medical Device Consulting  
5 Whitcomb Avenue  
Ayer, Massachusetts 01432

MAR 20 2007

Re: K063444

Trade/Device Name: Total Etch Bonding Agent (Total Etch Bond & Total Etch Dual Bond)  
Regulation Number: 21 CFR 872.3200  
Regulation Name: Resin Tooth Bonding Agent  
Regulatory Class: II  
Product Code: KLE  
Dated: March 01, 2007  
Received: March 07, 2007

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu S. Lin', with a stylized flourish at the end.

Chiu S. Lin, PhD

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K063444

Device Name: Total Etch Bonding Agent (Total Etch Bond & Total Etch Dual Bond)

**Indications for Use:**

**Total-Etch Dualbond** is indicated for:

- Bonding resin-based materials (especially dual-cure composite / compomer materials) to tooth structure (dentin and enamel)
- Treatment of hypersensitive teeth

**Total-Etch Bond** is indicated for:

- Bonding resin-based materials (especially light-cure composite / compomer materials) to tooth structure (dentin and enamel)
- Treatment of hypersensitive teeth

Prescription Use X  
(Per 21 CFR 801 Subpart D)

OR

Over-the -Counter Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



March 1, 2007  
Director of Medical Devices, General Hospital,  
Food and Drug Administration, Dental Devices

510(k) Number: K063444

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